MAR 10 2008

K072425

	Regulation: 21 CFR 872.3640 and 21 CFR 872.3630
Identification of Predicates and Summary of Substantial Equivalence	The JNE Implant System is substantially equivalent with respect to the intended use, design, risks, device characteristics and performance aspects to numerous cleared devices, including: 510(k) / Product / Manufacturer - K971196 / ENDOPORE ENDOSSEOUS DENTAL IMPLANT SYSTEM / INNOVA CORP. - K002513 / ASTRA TECH IMPLANTS - DENTAL SYSTEM / ASTRA TECH, INC. - K033984 / STRAUMANN DENTAL IMPLANT SYSTEM / INSTITUT STRAUMANN AG
Device Description	The JNE Implant System is an endosseous dental implant made of Ti-6Al-4V ELI alloy and consists of several components. Geometrically, the fixture is screw-type. An abutment is connected to the fixture through a tapered-joint. Fixtures are treated with sandblast and acid etching using scanning electron microscopy (SEM).
Intended Use and Indications	The JNE Implant System is a titanium alloy screw-type endosseous dental implant and endosseous dental implant abutment, which is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for a prosthetic device, such as an artificial tooth, in order to restore a patient's chewing function.
Performance Testing	Several tests were performed on the device. All tests demonstrated that the device is safe and effective, performs comparably to and is substantially equivalent to the predicate devices.

5. 510(k) Summary

Submitter/Contact Person	H. Carl Jenkins The **Wood Burditt** Group FDA Regulatory Counseling 1025 W. Everett Rd., Suite 100 Lake Forest, IL 60045 (ph) (847) 234-7500 x 205 (fax) (847) 574-0728 (email) hcjenkins@woodburditt.com
Applicant	GC America, Inc. 3737 W. 127th Street Alsip, IL 60803 800.323.3386 x4042 708.897.4042 708.897.4031 (fax)
Manufacturer	GC CORPORATION. 76 - 1 HASUNUMA - CHO , ITABASHI - KU TOKYO 174 - 8585 JAPAN
Sterilization Facility	RADIA INDUSTRY CO., LTD 168 OOYAGI, TAKASAKI GUNNMA 370 - 0072 JAPAN
Device Name	JNE Implant System
Common Name	Root-form Endosseous Dental Implant and Endosseous Dental Implant Abutment
Classification	Class II Procode DZE and NHA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

GC America, Incorporated
C/O Mr. H. Carl Jenkins
The Wood Burditt Group
1025 Everett Road, Suite 100
Lake Forest, Illinois 60045

MAR 10 2008

Re: K072425
Trade/Device Name: GC JNE Implant
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: January 28, 2008
Received: January 29, 2008

Dear Mr. Jenkins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

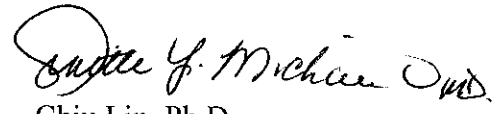
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): _____

Device Name: GC JNE Implant

Indications for Use:

The JNE Implant System is a titanium alloy screw-type endosseous dental implant and endosseous dental implant abutment, which is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for a prosthetic device, such as an artificial tooth, in order to restore a patient's chewing function.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072425